

### 3 510(k) SUMMARY

SEP 27 2011

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

The applicant is: Abbott Medical Optics Inc.  
1700 E. St. Andrew Place  
Santa Ana, CA 92705, USA

The contact person is: Ophelia Biggs  
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Date the summary was prepared: June 15, 2011

Subject device: Trade/Proprietary Name:  
AMO WHITESTAR Signature Phacoemulsification System

Classification Name:  
Phacofragmentation system

The device to which substantial equivalence is claimed:

510(k) Number	Clearance Date	Device	Manufacturer
K060366	April 7, 2006	Device Name: The AMO Ophthalmic Surgical System  Marketed as: AMO WHITESTAR Signature Phacoemulsification System, version 1.0	Abbott Medical Optics Inc. (formerly Advanced Medical Optics, Inc.)

#### 3.1 DEVICE DESCRIPTION SUMMARY

The subject device is the AMO WHITESTAR Signature Phacoemulsification System, which is an upgrade to the predicate device, The AMO Ophthalmic Surgical System (K060366, cleared in April 7, 2006). The predicate device is AMO's first-generation WHITESTAR Signature Phacoemulsification System. The subject device is classified under 21 CFR 886.4670 as a "phacofragmentation system," described as an AC-powered device with a

fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

The subject device is designed for use in performing anterior segment ophthalmic surgery (i.e., cataract). It is intended for use in performing phacoemulsification, diathermy, irrigation/aspiration, and vitrectomy. The system has a console for controlling the functions and powering the device; a display with a touch screen for selecting and activating functions; irrigation and aspiration lines; a foot pedal and remote control for controlling the device; an automated IV pole; a phacoemulsification handpiece for emulsifying the lens; and drainage packs. The materials, fundamental scientific technology, physical properties, and intended use of the subject device are identical to those of The AMO Ophthalmic Surgical System.

### 3.2 INDICATIONS FOR USE

The AMO WHITESTAR Signature Phacoemulsification System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements.

### 3.3 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

The AMO WHITESTAR Signature Phacoemulsification System is equivalent to its predicate device, the AMO Ophthalmic Surgical System (commercially marketed as the AMO WHITESTAR Signature phacoemulsification system, version 1.0) in terms of its intended use, technological characteristics, energy used, materials, chemical composition, manufacturing process, biocompatibility, and FDA-recognized standards used for performance testing. The subject device includes 1) a console for controlling the functions and for powering the device; 2) irrigation and aspiration lines for supplying balanced salt solution to and removing the fragmented lens and solution from the surgical site, respectively; 3) handpieces used for phacoemulsification, irrigation/aspiration, vitrectomy, and diathermy; 5) modular disposable tubing packs, which include fluid aspiration drainage bags; and 6) control accessories, including a remote control and a foot pedal. The system accessories used for the subject device are substantially equivalent to those used with the predicate device, the AMO Ophthalmic Surgical System.

The subject device provides the following main modes during anterior segment surgery: diathermy, phacoemulsification, irrigation/aspiration, and vitrectomy.

- The **Diathermy** (bipolar) mode is used to coagulate blood vessels during a surgical procedure and, in some cases, to coagulate the conjunctiva following a procedure.
- The **Phacoemulsification** mode is used to break up (emulsify) the nucleus of a lens, allowing it to be aspirated from the eye through a small incision.
- The **Irrigation/Aspiration** mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability by replacing aspirated material with a balanced salt solution. A peristaltic pump provides a predictable and stable aspiration rate. Irrigation is gravity-fed, and intraocular

pressure can be regulated by adjusting the height of the balanced salt solution bottle.

- The **Vitrectomy** mode is used to cut and remove vitreous from the anterior segment of the eye during secondary intraocular lens implantation, following vitreous loss associated with trauma, or during primary cataract surgery.

These surgery modes are substantially equivalent to the anterior segment surgery modes of the predicate device, the AMO Ophthalmic Surgical System.

The subject device, the AMO WHITESTAR Signature Phacoemulsification System, is an upgrade to the predicate device, the AMO Ophthalmic Surgical System, cleared in K060366. The materials, fundamental scientific technology, physical properties, and intended use of the subject device are identical to those of The AMO Ophthalmic Surgical System. The indications for use of the subject device are identical to those for the predicate device for anterior segment surgery. The subject device also includes technical modifications to address user feedback and an expanding customer base, improve ease of use, and facilitate system service without disrupting surgical procedures.

### **3.4 SUMMARY OF NON-CLINICAL TESTS**

The AMO WHITESTAR Signature Phacoemulsification System has undergone testing and is in compliance with the applicable requirements of safety standards. The subject device was found to perform equivalently to the predicate device during the following modes of anterior segment ophthalmic surgery: phacoemulsification, irrigation/aspiration, diathermy, and vitrectomy. Therefore, the subject device and the predicate device have similar safety, effectiveness, and performance profiles.

All materials coming into contact with the patient or the patient fluid path are the same as those in the predicate device and have been cleared in previous 510(k) filings.

### **3.5 SUMMARY**

The technological characteristics that determine the functionality and performance of the subject device, the AMO WHITESTAR Signature Phacoemulsification System, are substantially equivalent to those cleared under K060366 for anterior segment ophthalmic surgery. The AMO WHITESTAR Signature Phacoemulsification System will be manufactured in compliance with FDA and ISO quality system requirements. System validation and verification have demonstrated that the functional requirements and system specifications were met prior to commercial release.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WQ66-G609  
Silver Spring, MD 20993-0002

Abbott Medical Optics Inc.  
c/o Ms. Ophelia Biggs  
Senior Regulatory Affairs Specialist  
1700 E. St. Andrew Place  
Santa Ana, CA 92705

SEP 27 2011

Re: K111697  
Trade/Device Name: AMO WHITESTAR Signature Phacoemulsification System  
Regulation Number: 21 CFR 886.4670  
Regulation Name: Phacofragmentation System  
Regulatory Class: Class II  
Product Code: HQC  
Dated: August 24, 2011  
Received: August 25, 2011

Dear Ms. Biggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

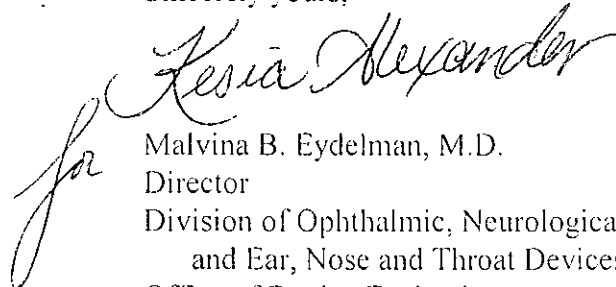
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Malvina B. Eydelman". To the left of the signature is a large, stylized handwritten "for" in cursive.

Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## 2 INDICATIONS FOR USE

510(k) Number (if known): K111697

Device Name: AMO WHITESTAR Signature Phacoemulsification System

### Indications for Use:

The AMO WHITESTAR Signature Phacoemulsification System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements.

Prescription Use X AND/OR Over-the-Counter Use \_\_\_\_\_  
Part 21 CFR 801.109 (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K111697